Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 14, 16-19, 27, 33, 34, 57, 60-63 are pending in the application, with claim 14 being the independent claim. Claims 1, 4-8, 11-13, 35, 37-39, 43, 44, 52 and 55 are sought to be canceled without prejudice to or disclaimer of the subject matter therein. New claims 60-63 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Reply to Restriction Requirement

In reply to the Examiner's restriction requirement requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby elect to prosecute the invention of Group II, represented by claims 14, 16-19, 27, 33, 34 and 57. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made without traverse.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

h

Rejection under 35 U.S.C. § 103

The Examiner rejected claims 14, 33 and 34 under 35 U.S.C. § 103(a) as being unpatentable over Tsang et al. (U.S. Patent No. 5,955,588). According to the Examiner:

Tsang et al. disclose a medical devices such as stunts [sic], catheters, prostheses etc (col. 9, lines 1-7), made of metal such as stainless steel (col. 13, lines 10-12) coated with heparin by reacting with derivative of chloro(chlormethyl)dimethylsilane (col. 9, Example 1).

Therefore given the teaching Tsang et al. a person of ordinary skill in the art would have found it obvious to react biopolymer with a silane having required functional group to react with biopolymer and other functional group which provides bonding with substrate surface.

Appl. No. 09/138,464, Paper No. 5, page 5, lines 1-6.

Applicants respectfully disagree with the Examiner's rejection.

There are several differences between the teachings of Tsang *et al.* and the medical device recited in rejected claim 14 which make the claimed invention nonobvious.

The Structure of Applicants' Coating Complex is Different From the Heparin-Silane Complex of Tsang et al.

The covalent heparin-silane complexes of Tsang *et al.* do not have the same chemical structure as the product of the reaction between a biopolymer and a silane having the functional groups recited in claim 14.

Sterne, Kessler, Goldstein & Fox P.L.L.C.

D

Tsang et al.

The covalent heparin-silane complexes described in Tsang *et al.* are referred to in Tsang *et al.* under general Formula II (see Tsang *et al.* col. 3, lines 15-21 and col. 6, lines 50-58) and are properly termed "carbamates" (see Tsang *et al.* col. 7, lines 4-8) or "carbonates". An organic carbamate (sometimes called a urethane) is a compound having the group -O-C(=O)-N-R and an organic carbonate is a compound having the group -O-C(=O)-O-R (Exhibit A; Van Nostrand's Scientific Encyclopedia 8th Ed., Considine, D.M., Ed., pp. 528 and 536, respectively (1995)), where R is heparin in Tsang *et al.* A closer study of Formula II of Tsang *et al.* reveals that the complex is defined by the structure:

silane-O-C(=O)-R₃-heparin,

where R_3 is either N (a carbamate) or O (a carbonate).

The Claimed Invention

The product of the reaction between a biopolymer and a silane having any of the functional groups recited in claim 14 does not possess the silane-O-C(=O)-R₃-biopolymer structure described in Tsang *et al*. The product of the reaction of an amino or hydroxyl group on a biopolymer (such as heparin) with each of the functional groups recited in claim 14 is summarized in the table below:



Functional group	Product of reaction with hydroxyl	Product of reaction with amino
isocyanate (silane-N=C=O)	silane-N-C(=O)-O-biopolymer	silane-N-C(=O)-N-biopolymer
isothiocyanate (silane-N=C=S)	silane-N-C(=S)-O-biopolymer	silane-N-C(=S)-N-biopolymer
ester (silane-C(=O)-OR)	silane-C(=O)-O-biopolymer	silane-C(=O)-N-biopolymer
anhydride (silane-C(=O)-O- C(=O)-R)	silane-C(=O)-O-biopolymer	silane-C(=O)-N-biopolymer
acyl halide (silane-C(=O)-X)	silane-C(=O)-O-biopolymer	silane-C(=O)-N-biopolymer
alkyl halide (silane-C-X)	silane-C-O-biopolymer	silane-C-N-biopolymer
epoxide (silane-C-C-R) O	silane-C(OH)-C-O-biopolymer	silane-C(OH)-C-N-biopolymer
aziridine (silane-C-C-R) N	silane-C(NH)-C-O-biopolymer	silane-C(NH)-C-N-biopolymer

The above table demonstrates that with each of the functional groups recited in claim 14, the product does not possess the silane-O-C(=O)- R_3 -biopolymer described in Tsang *et al.*

Non-Obviousness of Claimed Invention

There is no suggestion or motivation in Tsang et al. to react heparin with anything other than the final intermediate described in Scheme 1 (see Tsang et al., col. 5, lines 14-39) and



exemplified in Example 1 (see Tsang et al., col. 11, lines 5-30). In particular, there is no description, suggestion or motivation in Tsang et al. to prepare a coating for a medical device by reacting a biopolymer with a silane having an isocyanate, an isothiocyanate, an ester, an anhydride, an acyl halide, an alkyl halide, an epoxide, or an aziridine to produce a complex with any of the structures summarized in the table above. Furthermore, there is nothing in Tsang et al. to suggest modifying the carbamate or carbonate functional group on the silane with one of the recited groups in claim 14.

In the Absence of a Suggestion or Motivation to Modify the Prior Art Device, the Examiner Has Not Made a Prima Facie Case of Obviousness

It is by now well settled that in order to establish a *prima facie* case of obviousness, any suggestion or motivation to modify the teaching(s) of a reference must come from the prior art. *In re Laskowski*, 10 USPQ2d 1397, 1398 (Fed. Cir. 1989)("Although the Commissioner suggests that [the structure in the primary prior art reference] could readily be modified to form the [claimed] structure, '[t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification".); *Litton Industrial Products, Inc. v. Solid State Systems Corp.*, 225 USPQ 34(3), 38 (Fed. Cir. 1985)("The references fail not only to expressly disclose the claimed invention as a whole, but also to suggest to one of ordinary skill in the art modifications needed to meet all the claim limitations.")

There is nothing in Tsang *et al.* to suggest the device of claim 14. In particular, there is nothing in Tsang *et al.* which suggests the production of any silane-biopolymer coating complex

B

other than the silane-carbonate-heparin or silane-carbamate-heparin complexes of Formula II of Tsang *et al.* Without any motivation from the prior art to modify Tsang *et al.*, a *prima facie* case of obviousness has not been established.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. §103(a).

Dependent claims 33 and 34 are believed allowable for the same reasons discussed above for claim 14. Reconsideration and withdrawal of the Examiner's outstanding rejection of claims 33 and 34 is respectfully requested.

Indication of Allowable Subject Matter

Applicants thank the Examiner for the indication of allowable subject matter in claims 16-19, 27 and 57. The Examiner's objection to claims 16-19, 27 and 57 as being dependent upon rejected base claim 14 is overcome for the same reasons discussed above. Reconsideration and withdrawal of the examiner's outstanding objection is respectfully requested.

New Claims

New dependant claims 60-63 are directed to preferred functional groups on the silane and preferred heparin complexes. Support for the amendment to claim 19 and for new claims 60-63 is found in the original specification at page 5, lines 10-11; page 8, lines 17-18; page 8, line 19 though page 9, line 3; and elsewhere. The new claims are patentable for at least the same reasons discussed above for claim 14.



Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Van Nostrand Reinhold 115 Fifth Avenue New York, NY 10003

International Thomson Publishing Europe Berkshire House 168-173 High Holborn London WCIV 7AA England

Thomas Nelson Australia 102 Dodds Street South Melbourne, 3205 Victoria, Australia

Nelson Canada 1120 Birchmount Road Scarborough, Ontario Canada M1K 5G4 International Thomson Publishing GmbH Königswinterer Strasse 418 53227 Bonn Germany

International Thomson Publishing Asia 221 Henderson Road #05-10 Henderson Building Singapore 0315

International Thomson Publishing Japan Hirakawacho Kyowa Building, 3F 2-2-1 Hirakawacho Chiyoda-ku, 102 Tokyo Japan

International Thomson Editores Campos Eliseos 385, Piso 7 Col. Polanco 11560 Mexico D.F. Mexico

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1 2 3 4 5 6 7 8 9 10 ARCKP 01 00 99 98 97 96 95 94

Library of Congress Cataloging-in-Publication Data

Van Nostrand's scientific encyclopedia / Douglas M. Considine, editor. Glenn D. Considine, managing editor.—8th ed.

p. cm.

503-dc20

Includes bibliographical references and index.

ISBN 0-442-01864-9 (set).—ISBN 0-442-01865-7 (v. 1).—ISBN 0-442-01868-1 (v. 2.)

1. Science — Encyclopedias. 2. Engineering—Encyclopedias.

I. Considine, Douglas M.II. Title: Scientific encyclopedia.Q121.V3 1994

94-29100 CIP



(Macrodipteryx longipennis); the Pennant-Wing Mghtjar (Semeiophorus vexillarius); the White-Throated Poor-Will (Phalaenoptilus nuttallii); the Common Nighthawk (Chordeiles minor); and the Pauraque (Nyctidromus albicollis). See also Nightjars and Nighthawks.

CAPROIC ACID. Also called hexanoic, hexylic, or hexoic acid, formula CH₃(CH₂)₄COOH. Present in milk fats to extent of about 2%. Also a constituent of some edible vegetable oils. See Vegetable Oils (Edible). The acid is oily, colorless or slightly yellow, and liquid at room temperature. Odor is that of Limburger cheese. Soluble in alcohol and ether; slightly soluble in water. Specific gravity 0.9276 (20.4°C); mp -4.0°C; bp 205°C. Combustible. Caproic acid is derived from the crude fermentation of butyric acid; or by fractional distillation of natural fatty acids. Used in various flavorings; manufacture of rubber chemicals; varnish driers; resins; pharmaceuticals.

CAPROLACTAM. NH(CH₂)₅CO, formula weight 112.15, liquid ingredient used in the manufacture of type 6 nylon. See also Fibers. Several hundred million pounds of the compound are produced annually. There are a number of proprietary processes for caprolactam production. In one process, the chargestock is nitration-grade toluene, air, hydrogen, anhydrous NH₃, and H₂SO₄. The toluene is oxidized to yield a 30% solution of benzoic acid, plus intermediates and by-products. Pure benzoic acid, after fractionation, is hydrogenated with a palladium catalyst in stirred reactors operated at about 170°C under a pressure of 10 atmospheres. The resultant product, cyclohexanecarboxylic acid, is mixed with H₂SO₄ and then reacted with nitrosylsulfuric acid to yield caprolactam. The nitrosylsulfuric acid is produced by absorbing mixed nitrogen oxides N_2O_3 in H_2SO_4 : $N_2O_3 + H_2SO_4 \rightarrow SO_3 + 2NOHSO_4$. The resulting acid solution is neutralized with NH₃ to yield (NH₄)₂SO₄ and a layer of crude caprolactam which is further purified. The overall process reaction is:

COOH + NOHSO₄
$$\xrightarrow{SO_3}$$

$$CH_2 \longrightarrow CH_2 \longrightarrow CO$$

A later process utilizes a photochemical reaction in which cyclohexane is converted into cyclohexanone oxime hydrochloride:

$$C_6H_{12} + NOC1 \xrightarrow{HC1} C_6H_{10}NOH \cdot 2HC1$$

The yield of cyclohexanone is estimated at about 86% by weight. Then, in a Beckmann rearrangement, the cyclohexanone oxime hydrochloride is converted to ϵ -caprolactam:

$$C_6H_{10}NOH \cdot 2HCI$$
 $\xrightarrow{H_2SO_4}$ $CH_2 - (CH_2)_4 - C = O$ + 2HCI

CARACARA (Aves, Falconiformes). South American birds of several species related to the hawks. They eat carrion but also catch living prey and sometimes rob other birds of their prey. One species, Audubon's caracara, Polyborus cheriway, occurs in the extreme southern parts of the United States. The chimachima is found from Panama to southern Brazil. The chimango is found in Tierra del Fuego and the southern part of the continent. See also Falconiformes.

CARANGIDS (Osteichthyes). Of the order Percomorphi, suborder Percoidea, the family Carangidae, the carangids are very fast and many of the species are excellent food fishes. They are well distributed worldwide in tropical and temperate waters. There are about 200 species, most of which are shaped something like the yellow jack (Gnathanodon speciosus). The latter fish occurs in the Indo-Pacific and attains a length of about 3 feet (0.9 meter). It possesses several vertical greenish strips on a pale yellow body. The tail fin is sharply forked. The jack

mackerel (*Trachurus symmetricus*) frequents the waters of the American Pacific coast. These fish are characterized by a sharp ridge adjacent the caudal peduncle of the tail. This is formed by a series of bony plates, sometimes called scutes.

Another interesting carangid is the Atlantic pompano (Trachinotus carolinus), a valuable food fish. Possessed of spectacular blue coloration on the back, the dirigible-shaped Elagatis bipinnulatus (Indo-Pacific rainbow runner) attains a length of about 4 feet (1.2 meters). The yellow-tail (Seriola dorsalis) is a highly regarded sporting fish in the waters of Mexico and southern California and attains a length in excess of 3 feet (0.9 meter). The Naucrates ductor is the legendary pilot fish, reputed to lead ships and swimmers to safety. The legend has no foundation. The species of jack fishes frequenting the waters of the Palmyra Islands are reputed to be poisonous. However, a related species (Caranx melampygus), known as the black ulua, is widely sold in the Hawaiian Islands. The jacks and cavallas found in the Philippines are considered of premium commercial value, particularly when taken from the freshwater lakes on their return to the sea. Jacks are also found in New Guinea.

CARAPACE. A shield-like covering of the upper part of the body. In the crustaceans it is the body wall of the thorax and in the turtles and tortoises it is a complex structure made up of bony plates, including flattened ribs and vertebrae, covered with thin horny plates. The armor of the armadillo, composed of many bony plates developed from the skin and covered with horny plates, is also called a carapace.

CARAPATO (Arachnida, Acarina). Ticks of two species, found in tropical Africa and Central America, respectively. The African species is also called the tampan.

The wounds produced by these creatures are severe in themselves but their transmission of the germs of relapsing fever is a much greater danger.

CARBAMATES. Derivatives of the hypothetical carbamic acid, H_2NCOOH , which does not exist. The ethyl derivative urethane is prepared by heating urea in alcohol under pressure, by the reaction $H_2NC(=O)NH_2 + C_2H_5OH \rightarrow H_2NCOOC_2H_5 + NH_3$. The structures of representative carbamates are shown below:

$$OC \left\{ \begin{array}{c} OCH_3 \\ NH_2 \end{array} \right\} \qquad OC \left\{ \begin{array}{c} OC_2H_5 \\ NH_2 \end{array} \right\} \qquad OC \left\{ \begin{array}{c} SC_2H_5 \\ NH_2 \end{array} \right]$$

Methyl carbamate

Ethyl carbamate (urethane)

Thiourethane

CARBAMIC ACID. See Herbicide; Insecticide

and D are substituent groups. Their importance in elucidating the mechanism of organic reactions is because a considerable proportion of all organic reactions involve carbanions, as others do carbonium ions and carbon free radicals (including carbene radicals). Many carbanion reactions involve removal of a proton from a carboxylic acid to form a carbanion. Many electrophilic substitution reactions involve carbanions. Carbanions are strong bases or nucleophiles. Many electrophilic substitution reactions that have carbanion intermediates are base-catalyzed since the basic reagent produces the basic carbanion. Because of the negative charge on carbanions, their structures are affected by cations, by attached substituents and particularly by the solvent.

CARBENE. The name quite generally used for the methylene radical, :CH₂. It is formed during a number of reactions. Thus the flash photochemical decomposition of ketene (CH₂—C—O) has been shown to proceed in two stages. The first yields carbon monoxide and :CH₂, the latter then reacting with more ketene to form ethylene and carbon monoxide. Carbene reacts by insertion into a C—H bond to form a C—CH₃ bond. Thus carbene generated from ketene reacts with propane



Carbonates: Carbonic acid H_2CO_3 is present to the extent of 0.27% of the total CO_2 present in the solution that is formed by dissolving CO_2 in H_2O at room temperature. The CO_2 may be expelled fully upon boiling. The solution reacts with alkalis to form carbonates, e.g., sodium carbonate, sodium hydrogen carbonate, calcium carbonate, calcium hydrogen carbonate. The acid ionization constant usually cited for carbonic acid (4.2×10^{-7}) is actually for the equilibrium $CO_2(aq) + H_2O \rightleftharpoons H^+ + HCO^-_3$. The true ionization constant, i.e., for the equilibrium $H_2CO_3 \rightleftharpoons H^+ + HCO^-_3$ is about 1.5×10^{-4} . The carbonate ion is a resonance hybrid of the three structures shown a, b, and c as well as structures of the type d which give a partial ionic character to bonds. This resonance is somewhat inhibited in the acid and its esters, but is complete, or much more nearly complete, in many other derivatives and in the carbonate ion. Esters of both metacarbonic, $(RO)_2CO$, and orthocarbonic acid, $(RO)_4C$, are known. The esters also exhibit resonance.

Metallic carbonates are (1) soluble in H₂O, e.g., sodium carbonate, potassium carbonate, ammonium carbonate (2) insoluble in H₂O and excess alkali carbonate, e.g., calcium carbonate, strontium carbonate, barium carbonate, magnesium carbonate, ferrous carbonate (3) insoluble in H₂O but soluble in excess alkali carbonate forming carbonate complexes, e.g., compounds of uranium and ytterbium U(CO₃)₂, UO₂CO₃, Yb₂(CO₃)₃. Metallic bicarbonates are known in solution and on warming are converted into ordinary or normal carbonates, e.g., bicarbonates of sodium, potassium, calcium, barium. These are preferably named as "hydrogen carbonates," e.g., NaHCO₃ = sodium hydrogen carbonate. Basic carbonates are important in such cases as lead ("white lead"), zinc, magnesium, and copper. Carbonates of very weak bases, such as aluminum, iron(III), and chromium(III), are now known.

The carbonates are found in nature as the carbonates, calcite, iceland spar, limestone and various forms of impure calcium carbonate CaCO₃, as magnesite (magnesium carbonate, MgCO₃), as dolomite (various compositions of calcium and magnesium carbonates), as witherite SrCO₃, as strontianite SrCO₃, as azurite and malachite (various compositions of cupric hydroxycarbonates), in various natural waters as carbonic acid, calcium and magnesium hydrogen carbonates, in blood, as sodium hydrogen carbonate.

Many esters of carbonic acid are known, e.g., diethyl carbonate, ethyl ester of metacarbonic acid, $(C_2H_5O)_2CO$, made by reaction of ethyl alcohol and carbonyl chloride; dimethyl carbonate, $(CH_3O)_2CO$; methyl ethyl carbonate, $(CH_3O)CO(OC_2H_5)$; dipropyl carbonate, $(C_3H_7O)_2CO$; tetraethyl carbonate, ethyl ester of orthocarbonic acid, $(C_2H_5O)_4C$, bp 158°C.

Peroxycarbonic acid exists only in its compounds. Alkali peroxycarbonates are obtained by electrolysis of concentrated solutions of the carbonates, the anodic reaction being written as

$$2{\rm CO_3^{2-}} \to {\rm C_2O_6^{2-}} + 2_e^-$$

The peroxycarbonates are relatively stable only in concentrated alkaline solutions. On dilution they decompose to give the bicarbonate and hydrogen peroxide

$$Na_2C_2O_6 + 2H_2O \rightarrow 2NaHCO_3 + H_2O_2$$

when acidified, the peroxycarbonate ion gives, correspondingly, $\rm CO_2$ and hydrogen peroxide

$$C_2O_6^{2-} + 2H^+ \rightarrow 2CO_2 + H_2O_2$$

Carbonyls: The metal carbonyls are strongly covalent in character, as shown by their volatility, their solubility in many nonpolar solvents, and their insolubility in polar solvents. They also behave in many reactions like mixtures of carbon monoxide, CO, and the metal. Those of group 6b elements, $Cr(CO)_6$, $Mo(CO)_6$, and $W(CO)_6$ are more stable and less reactive than the others, especially those of group 8 elements. Group 7b carbonyls are $Mn_2(CO)_{10}$, $Tc_2(CO)_{10}$, and $Re_2(CO)_{10}$, while group 8 elements form $Fe(CO)_5$, $Fe_2(CO)_9$, $Fe_3(CO)_{12}$, $Co_2(CO)_8$, $Co_4(CO)_{12}$, $Ni(CO)_4$, $Ru(CO)_5$, $Ru_2(CO)_9$, $Ru_2(CO)_{12}$, $Rh_2(CO)_8$, $Rh_3(CO)_9$, (and multiples), $Rh_4(CO)_{14}$, (and multiples), $Os(CO)_5$, $Os_2(CO)_9$, $Ir_2(CO)_8$, and $Ir_3(CO)_9$ (and multiples). The carbonyls form a wide variety of addition compounds; they are dissolved in alcoholic potassium hydroxide or other strong alkalies to form hydrides which are acids, and can be used to form a wide variety of more complex compounds. Although $H_2Fe(CO)_4$ is a moderately weak acid, $pK_1 =$

4.44, $pK_2 = 14.0$, $HCo(CO)_4$ appears to be comparable with HCl in acidity. The carbonyl compounds have zero charge number on the metal. The mononuclear carbonyls are spin-paired complexes, and are formed only by metals having even atomic numbers. However, metals having odd atomic numbers can form carbonyl compounds with other atoms or radicals, as exemplified by the nitrosyl compound of cobalt carbonyl, $Co(CO)_2NO$, where the—NO radical contributes the electron necessary to complete the 3d level of the cobalt atom. More than one NO group may occur in a metal carbonyl, as, for example, in $Fe(CO)_2(NO)_2$. This is isostructural with $Co(CO)_3NO$ and $Ni(CO)_4$.

Halides: The four tetrahalides of carbon are symmetrical, planar compounds, with the general property of marked stability to chemical reactions, although the tetraiodide undergoes slow hydrolysis in contact with water to form iodoform and iodine. It also decomposes under the action of light and heat. The stability of these four compounds decreases in order of descending periodic table position. Their properties are given below:

Name	FORMULA	MP	BP
Carbon tetrafluoride	CF ₄	-184°C	-128°C
Carbon tetrachloride	CCl₄	-23.0°	-76.8°
Carbon tetrabromide	CBr ₄	$\left\{ \begin{array}{l} \alpha 48.48 \\ \beta 90.18 \end{array} \right\}$	-189.5°
Carbon tetraiodide	Cl₄	171° dec.	

The same relation of reactivity and stability to periodic position is exhibited by such other carbon halides as hexachloroethane $CCl_3 \cdot CCl_3$ and hexabromoethane, $Br_3 \cdot CBr_3$, as well as by hexachloroethylene, $CCl_2 = CCl_2$ and hexabromoethylene, $CBr_2 = CBr_2$. Carbon also forms halides containing more than one halogen. See also Carbon Tetrachloride.

It is well established that hydrogen forms more than one covalent binary compound with carbon. Fluorine behaves similarly. Thus, fluorine forms CF_4 , C_2F_4 , C_2F_6 , C_3F_8 and many higher homologs, as well as the definitely interstitial compound $(CF)_n$. The other halogens form some similar compounds, although to more limited extent, and various polyhalogen compounds have been prepared. They exhibit the maximum covalency of four and are therefore inert to hydrolysis and most other low temperature chemical reactions.

Carbon Oxides: See Carbon Dioxide; Carbon Monoxide; Carbon Suboxide.

The Fullerenes

The less-than-scientific ring ascribed to the comparatively recent discovery of a third form of carbon, the *fullerenes*, is reminiscent of *flavors* used a few years ago to describe the various kinds of quarks in the field of high-energy physics. The technical literature on fullerenes, as of early 1994, features such terms as bucky-ball, buckministerfullerene, buckytube, carbon cage, dopey ball, hairy ball, Russian doll, et al., some of which terms are synonymous; others have specific connotations. Considered as an entity, fullerene chemistry constitutes a major breakthrough in the science of physics and chemistry of materials at the molecular level.

The absence of a formal nomenclature at this juncture is accompanied by a somewhat fuzzy chronology pertaining to the discovery and early research on the fullerenes. However, the isolation and confirmation of the C_{60} all-carbon molecule sans any dangling bonds, as first conjectured in 1985, was pivotal to subsequent research.

Setting the Stage for Carbon 60 Research. The pathways that ultimately led to the geometric visualization of the C_{60} molecule were several and varied.

- (1) A growing interest in cluster configurations extends back to the 1950s. The sophistiction of instrumentation for investigating once exotic substances has improved many times over during recent years, and numerous schemes of molecular geometry have been proposed. Thus, in retrospect, the efforts made to visualize the structure of the C_{60} molecule were not exclusively of a pioneering bent.
- (2) For many years, astrophysicists have been interested in the role of carbon molecules, both as building blocks and as photofragments of carbonaceous materials. As early as 1972, polyyne chain molecules ($\cdot \cdot \subset = \subset \subset = \subset \subset = \subset \cdots$) were proposed as being present in interstell

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